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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,346	03/26/2004	Yoshinobu Yamazaki	Q80493	7551
23373	7590	07/16/2007		
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
			EXAMINER HENLEY III, RAYMOND J	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 07/16/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/809,346

**Applicant(s)**

YAMAZAKI ET AL.

**Examiner**

Raymond J. Henley III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**CLAIMS 1-19 ARE PRESENTED FOR EXAMINATION**

Applicants' amendment filed April 17, 2007 has been received and entered into the application. Accordingly, claims 2-11 have been amended. Accordingly, the objection to claims 2-11, as set forth in the previous Office action dated October 20, 2006 at page 2, has been overcome and thus is hereby withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejection - 35 USC § 103***

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al., (U.S. Patent No. 6,538,152) in view of Short et al., (U.S. Patent No. 6,720,014) and Guittard et al., (U.S. Patent No. 6,262,115), each of record, for the reasons of record as set forth in the previous Office action, *Id.*, at pages 2-6, which reasons are here incorporated by reference.

Applicants' remarks have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness.

In particular, Applicants have traversed the present rejection because Applicants indicate that they have discovered that the presently claimed phenoxyacetic acid derivatives suppress spontaneous small bladder contractions (involuntary detrusor contractions) and the prior art fails to disclose this activity.

The Examiner does not find this position to be persuasive of non-obviousness because it remains, for the reasons presented by the Examiner, the use of the presently claimed compounds for the treatment of overactive bladder would have nevertheless have been obvious to one of

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ordinary skill in the art. That Applicants' may have discovered a mechanism of action for the claimed compounds not recognized in the art is not indicative of non-obviousness where, as here, the same ultimate therapeutic objective as that which would have been obvious from the prior art is being claimed. It is well settled that for obviousness, it is not necessary that the prior suggest doing what Applicants are doing for the very same purpose as Applicants, (MPEP § 2144 "Rationale Different From Applicant's is Permissible").

Also, it has not been shown or established that the suppression of small bladder contractions produces any therapeutic result that is unexpectedly superior to that which would have been reasonable expected by one of ordinary skill in the art given the teachings in the art cited by the Examiner.

Respecting the secondary references, Short and Guittard, they remain properly cited for the purposes relied on by the Examiner, i.e., for showing that (i) urinary incontinence is a symptom of overactive bladder and (ii) that overactive bladder and urinary incontinence are synonymous, respectively. Applicants' remarks concerning these references do not diminish the Examiner's conclusion of obviousness based, in part, on those teachings specifically identified by the Examiner in these references.

Applicants have also pointed to Example 4 and Figs. 8 and 9 in the present specification where it is alleged that superiority is established. The data referred to does not overcome the Examiner's conclusion of obviousness because the present conclusion of obviousness does not even contain a presumption that the presently claimed compounds would have been reasonably expected to be equally effective as the muscarinic receptor antagonist tolterodine. Accordingly, the claims are deemed to remain properly rejected.

***Double Patenting***

Claims 1-19 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/599,203, (Atty. Docket No. Q96974) for the reasons of record as set forth in the previous Office action, *Id.*, at pages 6-7, which reasons are here incorporated by reference.

Applicants have elected not to address the present rejection on the merits at this time.

The rejection is deemed to remain proper for the reasons of record referred to above.

None of claims are currently in condition for allowance.

**THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Raymond J. Henley III  
Primary Examiner  
Art Unit 1614

July 9, 2007